



1646

PATENT  
ATTORNEY DOCKET NO. STEM1110-3#9  
IDS attached  
11/20/02

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Twardzik et al.  
Serial No.: 09/932,172  
Filed: August 17, 2001  
Title: TGF- $\alpha$  POLYPEPTIDES, FUNCTIONAL FRAGMENTS AND METHODS OF USE THEREFOR

Art Unit: 1646  
Examiner To be assigned

Commissioner for Patents  
Washington, D.C. 20231

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Sir:

TRANSMITTAL SHEET

Transmitted herewith for the above-identified application, please find:

- (1) An Information Disclosure Statement (2 pages);
- (2) A Form PTO-1449 ( 9 pages);
- (3) Ninety-three (93) References; and
- (4) Return postcard;

## CERTIFICATION UNDER 37 CFR §1.8

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, October 18, 2002, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231.

JASON BERRY

Name of Person Mailing Paper Jason Berry

Signature

Jason Berry

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In the Application of  
Twardzik et al.  
Application Serial No.: 09/932,172  
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Page 2

PATENT  
Attorney Docket No.: STEM1110-3

This Information Disclosure Statement is being filed prior to receipt of a First Office Action on the merits. Therefore, no fee is deemed necessary. However, the Commissioner is hereby authorized to charge any amounts required by this filing, or credit any overpayment, to Deposit Account No. 50-1355.

Respectfully submitted,

Date: 10/18/02

  
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**United States Patent & Trademark Customer No. 28213**



PATENT  
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INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. 1.97, enclosed are references relating to the above-identified application. For the convenience of the Examiner, these references are listed on the attached Form PTO-1449 and a copy of each is enclosed herewith.

It is respectfully requested that these references be considered in the examination of this application and their consideration be made of written record in the application file.

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FORM 1449 U.S. Department of Commerce Patent and Trademark Office <i>OCT 21 2002</i>	Docket No. STEM1110-3	Serial No.: 09/932,172
	Applicants: Twardzik et al.	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date: August 17, 2001	Group Art Unit: 1646

### U.S. PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA	4,742,003	05/03/1988	Derynck and Goeddel			
	AB	4,749,683	06/07/1988	Murphy and Rhodes			
	AC	4,863,899	09/05/1989	George J. Todaro			
	AD	4,863,902	09/05/1989	Amagase et al			
	AE	4,874,746	10/17/1989	Antoniades and Lynch			
	AF	5,102,870	04/7/1992	Florine and Smith			
	AG	5,229,493	07/20/1993	Folkman et al.			
	AH	5,328,986	07/12/1994	Folkman and Shing			
	AI	5,750,376	05/12/1998	Weiss et al.			
	AJ	5,814,308	09/29/1998	Ke Zhang			
	AK	5,851,832	12/22/1998	Weiss et al.			
	AL	5,885,956	03/23/1999	Nardi and Brand			
	AM	5,886,141	03/23/1999	Folkman et al.			
	AN	5,902,799	05/11/1999	Herrmann et al.			
	AO	5,980,885	11/09/1999	Weiss and Reynolds			
	AP	5,981,165	11/09/1999	Weiss and Reynolds			

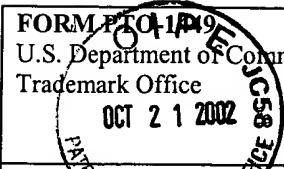
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Form 1449



U.S. Department of Commerce Patent and  
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**SUPPLEMENTAL INFORMATION  
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1646

	AQ	6,011,004	01/04/2000	Kessler and Apfel				
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	AW	6,326,201 B1	12/04/2001	Fung et al.				

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**FOREIGN PATENT DOCUMENTS**

EXAM. INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES/NO)
	AX	WO 84/01106	03/29/1984	PCT			
	AY	0 154 434 A1	09/11/1985	EP			
	AZ	WO 94/16718	08/04/1994	PCT			
	BA	WO 98/22127	05/28/1998	PCT			
	BB	WO 99/06060	02/11/1999	PCT			
	BC	WO 00/44400	08/03/2000	PCT			

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)**

	BD	Blikslager, Anthony T. et al., "Glutamine and Transforming Growth Factor- $\alpha$ Stimulate Extracellular Regulated Kinases and Enhance Recovery of Villous Surface Area In Porcine Ischemic-Injured Intestine," <i>Surgery</i> , Vol. 125, No. 2, February 1999, pgs. 186-194.
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Docket No.  
STEM1110-3Serial No.:  
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Applicants: Twardzik et al.

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	BF	Brand, Stephan A. et al., "Prolonged Efficacy of Islet Neogenesis Therapy with Gastrin and TGF $\alpha$ In Mature Rats with Preexisting Diabetes," <i>Diabetes</i> , Vol. 50 (Supplement), 2001, pg. A338.5630.
	BG	Burgel, Pierre-Regis et al., "Human Eosinophils Induce Mucin Production In Airway Epithelial Cells Via Epidermal Growth Factor Receptor Activation," <i>The Journal of Immunology</i> , 2001, pgs. 5948-5954.
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	BI	Chamberlin, Stephen G. et al., "Constrained Peptide Analogs of Transforming Growth Factor- $\alpha$ Residues Cysteine 21-32 Are Mitogenically Active," <i>The Journal of Biological Chemistry</i> , Vol. 270, No. 36, September 8, 1995, pgs. 21062-21067.
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	BK	Chou and Fasman, "Prediction of Protein Conformation," <i>Biochemistry</i> , Vol. 13, No. 2, 1974, pgs. 222-245.
	BL	Coffey, Robert J. et al., "Transforming Growth Factors and Related Peptides in Gastrointestinal Neoplasia," <i>Journal of Cellular Biochemistry</i> , Supplement 16G, 1992, pgs. 111-118.
	BM	Dayhoff, M.O. et al., "A Model of Evolutionary Change in Proteins," <i>Atlas of Protein Sequence and Structure</i> , 1972, pgs. 89-99.
	BN	De Larco, Joseph E. et al., "Sarcoma Growth Factor from Mouse Sarcoma Virus-Transformed Cells," <i>The Journal of Biological Chemistry</i> , Vol. 255, No. 8, April 25, 1980, pgs. 3685-3690.
	BO	Draoui, Muriel et al., "TGF $\alpha$ -PE40 Inhibits Non-Small Cell Lung Cancer Growth," <i>Life Sciences</i> , Vol. 54, No. 7, 1994, pgs. 445-453.
	BP	Dunbar and Goddard, "Structure-function and Biological Role of Betacellulin," <i>The International Journal of Biochemistry &amp; Cell Biology</i> , Vol. 32, 2000, pgs. 805-815.

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	BR	Egger, B. "Reduced Susceptibility of Mice Overexpressing Transforming Growth Factor $\alpha$ To Dextran Sodium Sulphate Induced Colitis," <i>Gut</i> , Vol. 43, 1998, pgs. 64-70.
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	BT	Ferrar, Isidre et al., "Transforming Growth Factor- $\alpha$ (TGF- $\alpha$ ) and Epidermal Growth Factor-Receptor (EGF-R) Immunoreactivity In Normal and Pathologic Brain," <i>Progress In Neurobiology</i> , Vol. 49, 1996, pgs. 99-123.
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	BV	Hardie, William D. et al., "Dose-Dependent Lung Remodeling In Transgenic Mice Expressing Transforming Growth factor- $\alpha$ ," <i>Am. J. Physiol. Lung Cell. Mol. Physiol.</i> , Vol. 281, 2001, pgs. L1088-L1094.
	BW	Hardie, William D. et al., "Attenuation of Acute Lung Injury In Transgenic Mice Expressing Human Transforming Growth factor- $\alpha$ ," <i>Am. J. Physiol.</i> , Vol. 277, 1999, pgs. L1045-L1050.
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	BW	Ibbotson, K.J. et al., "Tumor-Derived Growth Factor Increases Bone Resorption in A Tumor Associated with Humoral Hypercalcemia of Maignancy," <i>Science</i> , Vol. 221, pgs. 1292-1294.
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	CC	Jones, M.K. et al., "Gastrointestinal Mucosal Regeneration: Role of Growth Factors," <i>Frontiers in Bioscience</i> , Vol. 4, March 15, 1999, pgs. d303-309.
	CD	Kheradmand, Farrah et al., "Transforming Growth Factor- $\alpha$ Enhances Alveolar Epithelial cell Repair In a New In Vitro Model," <i>Am. J. Physiol.</i> , Vol. 267, 1994, pgs. L728-L738.
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	CF	Konturek, Peter Ch. Et al., "Epidermal Growth Factor and Transforming Growth Factor- $\alpha$ : Role In Protection and Healing of Gastric Mucosal Lesions," <i>European Journal of Gastroenterology &amp; Hepatology</i> , Vol. 7, 1995, pgs. 933-938.
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	CH	Kornblum, Harley I. et al., "Prenatal Ontogeny of the Epidermal Growth Factor Receptor and Its Ligand, Transforming Growth Factor Alpha, in the Rat Brain," <i>The Journal of Comparative Neurology</i> , Vol. 380, 1997, pgs. 243-261.
	CI	Kudlow, Jeffrey E. et al., "Inability of Anti-Epidermal Growth Factor Receptor Monoclonal Antibody to Block "Autocrine" Growth Stimulation in Transforming Growth Factor-Secreting Melanoma Cells," <i>The Journal of Biological Chemistry</i> , Vol. 259, No. 19, October 10, 1984, pgs. 11895-11900.
	CJ	Lefebvre, Ph. P. et al., "Regeneration of the Neurosensory Structures in the Mammalian Inner Ear," <i>Acta. Oto-rhino-laryngologica belg.</i> , Vol. 51, 1997, pgs. 1-10.

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	CK	Leong, Hoyee et al., "Cytostatic Effects of 3,3'-Diindolylmethane In Human Endometrial Cancer Cells Result from an Estrogen Receptor-Mediated Increase in Transforming Growth Factor- $\alpha$ Expression," <i>Carcinogenesis</i> , Vol. 22, No. 11, 2001, pgs. 1809-1817.
	CL	Liu, Dan et al., "TGF- $\alpha$ Can Act as Morphogen and/or Mitogen in a Colon-Cancer Cell Line," <i>Int. J. Cancer</i> , Vol. 56, 1994, pgs. 603-608.
	CM	Liu, Mark C. et al., "Allergy, Rhinitis, other Respiratory Diseases: Effects of Prednisone On the Cellular Responses and Release of Cytokines and Mediators After Segmental Allergen Challenge of Asthmatic Subjects," <i>Journal of Allergy and Clinical Immunology</i> , Vol. 108, No. 1, July 2001, 16 pages.
	CN	Liu, Ming et al., "Immunohistochemical Study of Transforming Growth Factor-Alpha in Human Lung Cancers," <i>Tumor Biol.</i> , Vol. 13, 1992, pgs. 294-298.
	CO	Lord, Bl. Et al., "Kinetics of Neutrophil Production in Normal and Neutropenic Animals During the Response to Filgrastim (r-metHu G-CSF) Filgrastim SD/01 (PEG-r-metHu G-CSF)," <i>Clin. Cancer Res.</i> , Vol. 7 July 2001, pgs. 2085-2090.
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	CQ	Marquardt, Hans et al., "Transforming Growth Factors Produced By Retrovirus-Transformed Rodent Fibroblasts and Human Melanoma Cells: Amino Acid Sequence Homology with Epidermal Growth Factor," <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 80, August 1983, pgs. 4684-4688.
	CR	Miettinen, Paivi J., "Transforming Growth Factor- $\alpha$ and Epidermal Growth Factor Expression in Human Fetal Gastrointestinal Tract," <i>Pediatric Research</i> , Vol. 33, No. 5, 1993, pgs. 481-486.
	CS	Mogi, Makio et al., "Interleukin-1 $\beta$ , Interleukin-6, Epidermal Growth Factor and Transforming Growth Factor- $\alpha$ are Elevated in the Brain from Parkinsonian Patients," <i>Neuroscience Letters</i> , Vol. 180, 1994, pgs. 147-150.

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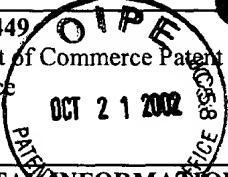
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	CT	Nestor, Jr., John J. et al., "A Synthetic Fragment of Rat Transforming Growth Factor $\alpha$ with receptor Binding and Antigenic Properties," <i>Biochemical and Biophysical Research Communications</i> , Vol. 129, No. 1, May 31, 1985, pgs. 226-232.
	CU	Ozanne, Brad et al., "Kirsten Murine Sarcoma Virus transformed Cell Lines and a Spontaneously Transformed rat Cell-Line Produce Transforming Factors," <i>Journal of Cellular Physiology</i> , Vol. 105, 1980, pgs. 163-180.
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	DE	Skolnick and Fetrow, "From Genes to protein Structure and Function: Novel Applications of Computational Approaches in the Genomic Era," <i>TIBTECH</i> , Vol. 18, January 2000, pgs. 34-38.
	DF	Song, Si young et al., "Expansion of Pdx1-Expressing Pancreatic Epithelium and Islet Neogenesis in Transgenic Mice Overexpressing Transforming Growth Factor $\alpha$ ," <i>Gastroenterology</i> , Vol. 117, 1999, pgs. 1416-1426.
	DG	Sottilli, Mauro et al., "Up-Regulation of Transforming Growth Factor $\alpha$ Binding Sites in Experimental Rabbit Colitis," <i>Gastroenterology</i> , Vol. 109, 1995, pgs. 24-31.
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	DI	Subauste and Proud, "Effects of Tumor Necrosis Factor- $\alpha$ , Epidermal Growth Factor and Transforming Growth Factor- $\alpha$ on Interleukin-8 Production By, and Human Rhinovirus Replication in, Bronchial Epithelial Cells," <i>International Immunopharmacology</i> , Vol. 1, 2001, pgs. 1229-1234.
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	DK	Twardzik, Danieal R. et al., "Similar Transforming Growth Factors (TGFs) Produced by Cells Transformed by Different Isolates of Feline Sarcoma Virus," <i>Virology</i> , Vol. 124, 1983, pgs. 201-207.
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	DN	Yang, Xiao-Dong et al., "Development of ABX-EGF, A Fully Human Anti-EGF Receptor Monoclonal Antibody, for Cancer Therapy," <i>Critical Reviews in Oncology/Hematology</i> , Vol. 38, 2001, pgs. 17-23.

EXAMINER	DATE CONSIDERED
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<b>FORM PTO-1449</b> U.S. Department of Commerce's Patent and Trademark Office  <i>OCT 21 2002</i> <small>PC TRADEMARKS</small>	Docket No. STEM1110-3	Serial No.: 09/932,172
	Applicants: Twardzik et al.	
<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Filing Date: August 17, 2001	Group Art Unit: 1646

	DO	Zhang, Maobin et al., "Transforming Growth Factor $\alpha$ and a PC 12-Derived Growth Factor Induce Neurites in PC12 Cells and Enhance the Survival of Embryonic Brain Neurons," <i>Cell Regulation</i> , Vol. 1, June 1990, pgs. 511-521.
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